



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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NOV 8 2005

Stuart M. Pape
Patton Boggs LLP
2550 M Street, NW
Washington, DC 20037

Re: Docket No. 2004P-0223/CP1

Dear Mr. Pape:

This letter is in response to the citizen petition you submitted to the Food and Drug Administration (FDA) under Title 21 of the Code of Federal Regulations (CFR) 10.30(a), on behalf of General Mills, Inc., requesting that FDA develop definitions for "excellent source," "good source," and "made with" as descriptors for the whole grain content of foods. FDA filed the petition on May 11, 2004. The petition states that these definitions should be promulgated under the Agency's authority in sections 201(n), 403(a) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) to prevent false and misleading food labeling statements. In accordance with 21 CFR 10.30(e)(3), this letter is to advise you that FDA is denying your petition.

The petition states that the descriptors for whole grain, i.e., "excellent source," "good source," and "made with," are neither nutrient content nor health claims. In addition, the petition states that "whole grain" is a substance and not a broad category of food. Further, the petition provides for levels of whole grains for each descriptor that must be met per labeled serving.¹ The petition states that fiber is a useful analytical tool for determining whole grain content and uses fiber as a surrogate marker for the method to evaluate whether the product meets the requisite levels of whole grains for each descriptor. A table in the petition lists the amount of fiber for each whole grain. If a product contains a blend of whole grain sources, the petition presents a weighted average of the grains most prevalent in the United States diet. The resulting fiber content to use as a marker for whole grain blends is 11.1 g of fiber/100g of whole grain blend.

Your petition raises a question for the agency about whether "whole grains" should be considered a food category, food ingredient, nutrient, or something else. The agency posed a question in the advance notice of proposed rulemaking on qualified health claims (68 FR 66040, November 25, 2003) (hereinafter "QHC ANPRM") requesting comments, among other things, on dietary guidance statements. Specifically, the agency asked whether the statement, "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may help reduce the risk of heart disease and certain cancers" properly refers to a substance or a broad category of food.² Comments received

¹ The petition states that "excellent source" of whole grain requires 16 grams (g) or more per labeled serving, "good source" requires 8-15 g per labeled serving, and "made with" requires at least 8 g per labeled serving.

² This statement is used as a health claim on food labels and was submitted to the agency in 1999 by General Mills, Inc. in the context of a health claim notification (section 403(r)(3)(C) of the act (21 U.S.C. 343(r)(3)(C))).

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on the QHC ANPRM voiced differing positions on this issue that we need to further consider.

The agency has considered certain statements about whole grains, such as "excellent source of whole grains," as implied nutrient content claims about fiber. In the final rule published on January 6, 1993, for nutrient content claims (58 FR 2302 at 2374) FDA stated that:

[T]he agency considers that a claim that a product is made with or otherwise contains a whole grain, a bran, or any type of dietary fiber (such as soluble fiber), implies that the product is a good source of total dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber derived largely from the sources of fiber mentioned such that the product met the definition for "good source of dietary fiber." However, a claim naming these ingredients that also used the term "high" or a synonym thereof would be misleading if the product was not "high in dietary fiber."

Moreover, the use of certain terms, such as "excellent source" and "good source," in conjunction with "whole grain" clearly resemble nutrient content claims. Based on what we stated about whole grains as an implied claim about fiber in the 1993 nutrient content claim final rule, the use of such terms with whole grains would be considered to be implied nutrient content claims about the fiber in whole grains. "Excellent source" and "good source" have been defined for use with nutrients that have an established reference daily intake (RDI) or daily reference value (DRV) in nutrient content claims (21 CFR 101.54). There is no RDI or DRV for whole grains.

Questions about how to classify certain label statements, e.g., as dietary guidance, nutrient content claims or health claims, have significant regulatory implications, not only for whole grains but also for other items in the diet that may be similarly situated. The agency believes that a decision related to the classification of certain label statements, such as those statements you request in your petition, needs to include consideration of scientific evidence that suggests that the health benefits of whole grains are based on more than their fiber content³ and the comments received in response to the QHC ANPRM on classification of whole grains as a food category or substance. Further, the agency believes that a decision should include a broader context of statements, not just those with respect to whole grains, and should include an opportunity for public input. Because the agency first needs to decide the appropriate classification of certain label statements before considering whether to publish a proposed rule for such statements under its authority in sections 201(n), 403(a) and 701(a) of the act or some other authority, it is denying your request.

Although FDA is denying your petition, the agency acknowledges the need for action on this topic. The recommendations from the recent "Dietary Guidelines for Americans" 2005 demonstrate that consumers can benefit from increased consumption of whole grains. We

³ See *Dietary Guidelines for Americans*, 2005.

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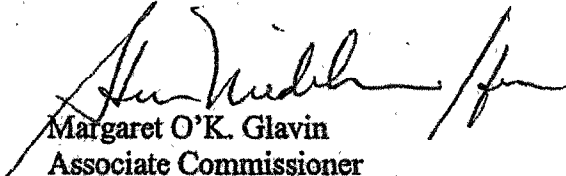
are reviewing options for public input on how to classify certain statements about food, including dietary guidance statements. Our review includes possible approaches on how to provide useful information to the public on whole grains. In addition, we are considering the development of guidance on what we consider the term "whole grains" to include.

Please be advised that manufacturers can currently use factual statements on foods labels such as "10 grams of whole grains" and "100% whole grain oatmeal" (as percentage labeling under 21 CFR 102.5(b)), provided that the statements are not false or misleading.

Conclusion

Therefore, as discussed above, because there are important questions for the agency to resolve related to the classification of certain label statements on foods, including those for whole grains, the agency is denying your petition.

Sincerely yours,


Margaret O'K. Glavin
Associate Commissioner
for Regulatory Affairs
Food and Drug Administration

